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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,071	02/03/2000	NORBERT O. REICH	30794.30USWO	1444

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/485,071

Applicant(s)

REICH ET AL.

Examiner

Patrick T. Lewis

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31, 34 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 34, 36-45 and 47-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 27.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of claims relating to GC box pMET, SEQ ID NO: 10 in Paper No. 26 dated August 28, 2003 is acknowledged. The traversal is on the ground(s) that 1) each of the pending claims relates to a single inventive concept; 2) examination of previously allowed claims cannot be burdensome; and 3) restriction after final action is improper. This is not found persuasive.

As set forth in the Office Action dated July 28, 2003, PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. Contrary to applicant's assertion, the corresponding technical feature is a 5mCpG dinucleotide, wherein 5mC is a C-5 methylcytosine, which is shown by Volpe et al. FEBS Letters (1991), vol. 329, pages 233-237 (Volpe), to lack novelty or inventive step (see page 233, second column) and does not make a contribution over the prior art.

Regarding applicant's arguments with regards to burdensome search and restriction practice after final are noted; however, they are not germane to the instant lack of unity requirement. The examiner is not required to show that a search would be burdensome. Furthermore, a Request for Continued Examination was filed November 15, 2003 (application is not in After Final status).

Art Unit: 1623

In the absence of a suggestion as to how specific sequences relate generically to one another, the requirement to select a specific sequence is maintained. The requirement is still deemed proper and is therefore made FINAL.

2. Claim 34, 36-45, and 47-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 26 dated August 28, 2003.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Flynn et al. *Biochemistry* (1996), Vol. 35, pages 7308-7315 (Flynn).

Flynn discloses the deoxyoligonucleotide GC-box b<sup>met</sup> which anticipates the synthetic oligonucleotide as instantly claimed (page 7309, Table 1).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1623

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn et al. *Biochemistry* (1996), Vol. 35, pages 7308-7315 (Flynn).

Claim 46 is drawn to a composition comprising a synthetic oligonucleotide of at least 26 nucleotides in length comprising a 5mCpG dinucleotide, and wherein the synthetic oligonucleotide comprises a phosphorothioate nucleotide, and a pharmaceutically acceptable carrier.

Art Unit: 1623

Flynn teaches the deoxyoligonucleotide GC-box  $b^{\text{met}}$  which is within the scope of the synthetic oligonucleotide as instantly claimed (page 7309, Table 1). Flynn differs from the instantly claimed invention in that Flynn does not explicitly teach a composition comprising a pharmaceutically acceptable carrier. However, claiming an unpatentable compound in combination with a carrier does not render the combination patentable if it would be obvious in the prior art to utilize a carrier with the compound. In the instant case, it would have been obvious to one of ordinary skill in the art at the time of the invention to add a pharmaceutically acceptable with the deoxyoligonucleotide GC-box  $b^{\text{met}}$  since Flynn teaches that the deoxyoligonucleotide containing CpG dinucleotide were designed to mimic DNA transcriptional cis elements previously reported to have cytosine C-5 methylated regulation (Abstract). DCMTase catalyzes DNA methylation, and DCMTase activity has been linked to tumor development (page 7308, column 2). The prior art in itself is seen to provide ample motivation for making the instantly claimed invention.

### ***Conclusion***

9. Claims 31, 34, and 36-50 are pending. Claims 34, 36-45, and 47-50 are drawn to a nonelected invention. Claims 31 and 46 are rejected. No claims are allowed.

Art Unit: 1623

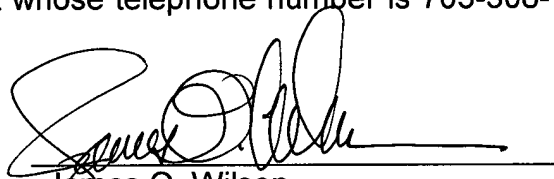
***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

ptl  
October 24, 2003